Special Project: Primary Angioplasty

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Table of Contents

List of Attachments:

Special Project: Primary Angioplasty

I. Objectives of the Special Project

A. to provide a mechanism for hospitals that do not have on-site open heart surgery the capacity to perform primary angioplasty.

B. to provide the Department of Public Health (Department) with relevant information to assist in its assessment of the safety and efficacy of the performance of primary angioplasty in hospitals without on-site cardiac surgery.

II. Description of the Special Project

A. Participant hospitals must:

1. meet minimum requirements for application.
2. complete prescribed training and ongoing education programs.
3. establish a collaborative relationship with a tertiary hospital that has on site open-heart surgery.
4. establish a Joint Quality Assurance Committee with the relevant collaborating tertiary hospital.
5. adhere to the Special Project protocol including the selection of patients, data collection, in-service education and notification of the Department of any serious events involving a patient.
6. collect and archive, on site, all data required by the Department.
7. perform a minimum of 36 primary angioplasty procedures/year.
8. submit all cases of patients that are entered into the Special Project to a group of physicians, designated by the Department, for a peer review process until a total of 150 primary angioplasty procedures have been performed and reviewed (Phase I).

B. Participant hospitals will be permitted to perform primary angioplasty, without ongoing peer review, after the performance and review of 150 cases *if* the peer review process results in a positive recommendation (Phase II). The Department may require random reviews.

III. Participation in the Special Project

A. Hospitals participating in the Special Project on November 23, 1999:

1. are permitted to continue to perform primary angioplasty under the Special Project;
2. are subject to all current requirements of the Special Project;
3. must appoint a "Physician Director", "Nurse Coordinator" and "Data Coordinator" for the Special Project at that hospital. The Physician Director is responsible for assuring that the Special Project hospital's program is in full compliance with all requirements of the Special Project at that hospital. The Physician Director and the Nurse Coordinator will serve as the staff contacts for all parties. The Data Coordinator assures that all required data is collected and archived in patient charts; and
4. must submit a letter to the Department which includes the following information:
   a. Names and phone numbers of "Physician Director", "Nurse Coordinator" and "Data Coordinator".
   b. A statement that all staff, including the interventional cardiologists, are currently ACLS certified.

c. Hours of availability of primary angioplasty services. Will staff be "on call" to respond to any emergent patients during the "off hours" of the cardiac catheterization service? If yes, what hours?
d. Description of availability of anesthesia services relative to the provision of angioplasty services.
e. Detail the projected number of angioplasty procedures per month, which will be performed to meet the requirements of 18 primary angioplasty procedures/6 month period. Please include a description of the assumptions used for this projection.
f. Copy of the hospital's policies and procedures regarding the establishment, maintenance and monitoring of the proficiency of all interventional cardiologists as a member of the team performing primary angioplasty at the Special Project hospital.
g. Copy of signed "Collaboration Agreement" with tertiary hospital.
h. A statement by an authorized agent of the Special Project hospital that the hospital agrees to pay all fees and expenses incurred in the implementation of the Special Project at the hospital.

B. For hospitals not participating as of November 23, 1999, but wishing to participate in the Special Project, the following process will be followed:
1. The applicant hospital shall appoint a "Physician Director", "Nurse Coordinator" and "Data Coordinator" for the Special Project at that hospital. The Physician Director is responsible for overseeing the development and implementation of the Special Project at that hospital. The Physician Director is also responsible for assuring that the Special Project hospital's program is in full compliance with all requirements of the Special Project at that hospital. The Physician Director and the Nurse Coordinator will serve as the staff contacts for all parties. The Data Coordinator assures that all required data is collected and archived in patient charts.
2. The applicant hospital shall submit a letter of application to the Department (See Attachment A).
3. The Department will review the information submitted. If the Department determines that the applicant hospital sufficiently meets the criteria for participation in the Special Project the Department will notify the hospital that it may contract with a party designated by the Department to provide the "C-PORT training" program.
4. The applicant hospital will then procure a current, signed collaboration agreement (See VI and Attachment B) with a tertiary hospital that has on site open-heart cardiac surgery services (tertiary hospital).
5. The "C-PORT" trainer will notify the Department when an applicant hospital has successfully completed the training program.
6. The Nurse Coordinator will notify the Department upon completion of the process to develop nursing care plans and critical pathways for the care of patients undergoing primary angioplasty procedures at the Special Project hospital.
7. Upon notification of the successful completion of the "C-PORT training" program; the completion of the process to develop nursing care plans and critical pathways; and receipt of a signed Collaboration Agreement, which is acceptable to the Department, the Department will issue a letter of approval for the hospital to perform primary angioplasty within the stipulations of the Special Project.

8. The hospital may then commence participation in Phase I of the Special Project (See VIII, A).

IV. **Minimum** criteria for application to participate in the Special Project

A. Each applicant hospital must:

1. have a fixed site cardiac catheterization service, which has been licensed for a period of not less than 3 years.
2. have performed ***at least*** 300 diagnostic catheterizations in each of the previous 2 years.
3. operate the cardiac catheterization service full time, at a minimum 5 days/week, 8 hours/day.
4. submit the number of patients/year with a diagnosis of ST-segment elevation AMI (includes LBBB, thrombolytic eligible and ineligible) that present at the hospital's ED during each of the 2 years prior to applying to participate in the Special Project.
5. submit a completed log (See Attachment C) of patients that present at the emergency room with a diagnosis of AMI (See VII, A) for a recent eight week period.
6. submit the number of doses of thrombolytic medication, issued through its pharmacy, to patients with a diagnosis of AMI during each of the 2 years prior to applying to participate in the Special Project.
7. have ***at least*** 2 physicians on the staff who will actively participate in the performance of primary angioplasty procedures at the Special Project hospital. In each of the previous 2 years each of these physicians shall have performed no fewer than 100 cardiac catheterization procedures (total diagnostic and therapeutic) of which at least 75 were angioplasty procedures.
   Each of the physicians participating in the Special Project will maintain credentials at a hospital at which that operator performs elective angioplasty procedures.
8. have staff and services consistent with the Clinical Practice Guideline Number 10 "Unstable Angina: Diagnosis and Management" published by the Agency for Health Care Policy and Research, including:
   a. the Emergency Department is continuously staffed by personnel competent in performing an ECG, initial evaluation and treatment of patients with acute ischemic syndromes including myocardial infarction and unstable angina. Appropriate monitoring equipment will be available, staff will be trained in cardiac monitoring and advanced cardiac life support (ACLS), and staff will maintain current ACLS certification.
   b. ability to provide routine lab testing and radiographic studies.
   c. intensive care unit usually has a nurse to patient ratio of 1:1 or 1:2, cardiac monitoring, immediate access to persons trained in ACLS; and capabilities for arterial line and pulmonary artery catheter placement, temporary pacemaker placement and mechanical ventilation. ICU staff are competent in the administration of all forms of vasoactive continuous IV infusions. Nursing staff are competent in the recognition and treatment of arrhythmias and evaluation of ischemic symptoms.

d. intra-aortic balloon equipment and staff trained in the use of this equipment are immediately available.
e. intermediate care unit usually has a nurse to patient ratio of 1:3 to 1:5; can provide continuous ECG monitoring and prompt access to personnel trained in ACLS, with current ACLS certification. Personnel are competent in recognition of arrhythmias and evaluation of ischemic symptoms; in the administration of some forms of vasoactive drips [e.g., low-dose dopamine, dobutamine, or nitroglycerine (NTG) infusion]; and in the care of patients with a temporary pacemaker already in place.

V. Required preparation for participation in the Special Project

A. "C-PORT" training: the Physician Director and Nurse Coordinator of the C-PORT trial have developed a formal training program for all staff in hospitals that do not have angioplasty capabilities. This training program will serve as the model that each hospital must complete prior to approval, by the Department, for participation in the Special Project. At a minimum this training will include:

1. Didactic presentations
2. Minimum of 2 days (8 hours each) of "one on one" observational training for all nurse-level caregivers and catheterization technical staff at the relevant tertiary hospital
3. If any member of the nursing or technical staff is to serve as a "second operator" during the angioplasty procedures, those individuals must undergo additional training. This training requires "hands-on" experience performing elective angioplasty at a tertiary center under the supervision of the Physician Director of the Special Project, or his designee, at the relevant tertiary hospital. The trainee will participate in a minimum of 25 elective angioplasty procedures. The training physician will determine the competence of the trainee to perform as the second operator.
4. Minimum of one "dry run" or "run through" by the staff at the Special Project hospital supervised by the "C-PORT" training staff. The "C-PORT" training staff will determine if additional "dry runs" are required.
5. The first five patients that are selected to have a primary angioplasty procedure performed must have the procedure monitored by the "C-PORT" training staff. The "C-PORT" training staff will review the adherence to protocol and local logistics (process indicators), quality of care, angiographic and medical outcomes and complications (outcomes indicators), for each patient. Steps will be taken to correct any deficiencies identified. At the discretion of the training staff additional monitoring of procedures may be required.

B. Nursing care plans and critical pathways

1. Following the initial didactic and observational training sessions, nursing personnel at the Special Project hospital will, with the assistance of staff from the relevant tertiary hospital and the "C-PORT" training staff, develop detailed nursing care plans and critical pathways for patients having primary angioplasty procedures performed.
2. The nursing care plans and critical pathways will, at a minimum, include pre-procedure, intra-procedure and post-procedure care.

3. The nursing care plans and critical pathways must be in place prior to the initiation of primary angioplasty services at the Special Project hospital.

VI. Collaborative association with tertiary hospital

A. All hospitals participating in the Special Project must:

1. establish a collaborative association with a tertiary hospital to specifically meet the requirements of the Special Project.
    a. the purpose of this association is to provide the Special Project hospital's staff ongoing support and expertise in the care of patients undergoing a primary angioplasty procedure.
2. procure a signed, current collaboration agreement with a tertiary hospital. **Note**: Hospitals that participated in the C-PORT study must procure and submit a new collaboration agreement specific to the requirements of this stage of the Special Project.

B. Responsibilities of the tertiary hospital shall, at a minimum, include:

1. Provision of ongoing, 24 hour availability of consultation to the physicians and nursing staff in the care of patients that are candidates for and/or have primary angioplasty performed.
2. Development with and participation in a ***joint*** quality assurance program, with the participant hospital, which includes all disciplines (i.e., physicians, nurses and technicians from the staffs of both the participating Special Project hospital and the collaborating tertiary hospital) providing patient care and focuses on patient outcomes.
3. Provision for occasions of clinical training, at the tertiary hospital, of the staff of the Special Project hospital in preparation for performing primary angioplasty at the Special Project hospital.
4. Development with the participant hospital of a training program for all staff (including, at a minimum, all interventional cardiologists, nurses and technicians) that are hired *after* the completion of the "C-PORT" training at the Special Project hospital. The training program will mirror the "C-PORT" training program.
5. Development with and participation in ***joint*** in-service education programs for *all staff* (including physicians, nurses and technicians) at the Special Project hospital. The in-service education programs will be based upon needs identified in the processes of staff evaluation and the QA program.

C. The Collaboration Agreement will:

1. be specific to the requirements of the Special Project and be developed through the participation of all appropriate disciplines. At a minimum, this includes physicians, nurses and hospital administrators from the staffs of both the participating Special Project hospital and the collaborating tertiary hospital. See Attachment B for Guidelines to be used in the development of the Collaboration Agreement.
2. delineate the development of a ***joint*** quality assurance review program which includes physicians, nurses and administrators from the staffs of both the participating Special Project hospital and the collaborating tertiary hospital and focuses on patient outcomes (See VII, G).
3. delineate the development of ***joint*** educational programs to include all groups of staff (physicians, nurses and technicians) at the Special Project hospital (See IX, C).

4. include specific provisions for the emergency and routine transfer of patients.

VII. Protocol

A. Clinical protocol

1. Clinical selection criteria

The following criteria must be met for the selection of patients for the performance of primary angioplasty:

a. The patient is 18 or more years of age.

b. The patient has no childbearing potential or has a negative pregnancy test.

c. The patient presents with:

1. > 30 minute ongoing ischemic cardiac pain

and

2. > 0.1 mv ST-segment elevation in 2 or more contiguous ECG leads
or
new or suspected new LBBB (ST-segment elevation infarction group)
or
> 0.1 mv ST-segment depression in V1 and V2 consistent with true posterior infarction

and

3. who arrives in the ER < 12 hours after symptom onset.

and

4. for whom coronary angiography shows TIMI 2 or less flow in the infarct related artery.

2. Clinical exclusion criteria

Patients will be excluded from primary angioplasty procedures at a Special Project hospital if any of the following conditions apply:

a. The patient's symptoms of a myocardial infarction began > 12 hours prior to presentation at the Special Project hospital's Emergency Department.

b. The patient has a sensitivity to contrast dyes which cannot be adequately pretreated with diphenhydramine and/or steroids.

c. The patient has severe peripheral vascular disease with inability of the operator to obtain vascular access.

3. For patients treated "unsuccessfully" with thrombolytics:

a. Within the 1.5 to 6 (> 1.5 and <6) hours after the initiation of the administration of a thrombolytic agent if the syndrome of chest pain and ST-segment elevation (> 1mm in 2 or more adjacent leads) *continues*; and coronary angiography shows both high grade (> 80%) stenosis and slow flow (TIMI 2 or less flow) in the infarct-related artery, "rescue angioplasty" may be performed.

b. In the absence of severe stenosis (>80%), slow flow (TIMI 2 or less flow), and persistent ST-segment elevation, however, chest pain alone ***is not*** a sufficient indication for the performance of "rescue angioplasty" after thrombolytic therapy, and ***is not*** permitted under the Special Project.

4. For patients in cardiogenic shock:

a. Cardiogenic shock is defined by clinical and/or hemodynamic criteria as follows:

1. hypotension (systolic pressure less than 90mmHg for 30 minutes or blood pressure requiring pressor support to keep the systolic blood pressure greater than 90mmHg) and/or

2. end organ hypoperfusion manifested by cool extremities and/or urine output less than 30cc per hour and/or
3. hemodynamics required for a diagnosis of primary left ventricular failure are heart rate > 60 beats per minute, cardiac index $\leq$ 2.2 L/min/M², pulmonary capillary wedge pressure > 15mmHg

b. Physicians may choose to either perform angioplasty on site, at the participating hospital, or to emergently transfer the patient to a tertiary hospital with on-site open-heart surgery.

5. Primary angioplasty should not be performed if:
   a. the infarct related artery cannot be identified
   b. there is severe triple vessel disease best treated with CABG
   c. there is > 50% stenosis of the main coronary artery
   d. there is TIMI 3 flow in the infarct related artery. An extremely unusual exception to this may be the rare circumstance of severe residual stenosis (>90% diameter stenosis) and evidence for ongoing ischemia (persistent chest pain and ST-segment elevation) without any other demonstrable cause, despite what appears to be TIMI 3 flow in the infarct-related artery.
6. See Attachment D for suggested "Guidelines for Clinical Care".

B. Informed consent
Consent for the performance of a cardiac catheterization procedure and possible angioplasty is to be obtained consistent with the policies and procedures of the hospital. The signed "Informed Consent" form is to be archived in the patient's hospital chart.

C. Notification of ambulance service
A fax will be sent to a local ACLS-capable ambulance company informing that service of the ongoing procedure (primary angioplasty) and its location. This is to allow the ambulance service sufficient opportunity for the allocation of services and to guarantee response time of no greater than 30 minutes.

D. Anesthesia services
Physician anesthesia services shall be immediately available on site when primary angioplasty procedures are performed.

E. Notification of Department
1. Hospitals participating in the "Special Project: Primary Angioplasty" must immediately (within 24 hours of the event or on the first business day following the event) report the following events to the Department by telephone:
   a. Death within 24 hours of the cardiac catheterization procedure or hospital discharge.
      1. *Cardiac death* is defined as death due to any of the following:
         a. Acute myocardial infarction;
         b. Cardiac perforation/pericardial tamponade;
         c. Arrhythmia or conduction abnormality;
         d. Cerebrovascular accident related to, or suspected of being related to, the cardiac catheterization procedure;
         e. Death due to complication of the procedure including bleeding, vascular repair, transfusion reaction, or bypass surgery; or
         f. Any death in which a cardiac cause could not be excluded.
      2. *Non-cardiac death* is defined as a death not due to cardiac causes (as defined above).

b. Cerebrovascular accident. This is defined as acute neurological deficits recorded by clinical staff that persisted >24 hours. Report if these events occurred:
    1. during the index catheterization;
    2. during the index hospitalization
c. Emergency CABG within 24 hours of procedure or hospital discharge. "Emergency" is defined as a sudden and often life-threatening mishap that arises in the course of and *as a result of* the performance of a cardiac catheterization and/or angioplasty procedure. This does not include patients either transferred directly from the cardiac catheterization procedure room or taken within 24 hours to the operating room for surgical correction of emergent/life threatening cardiac disease.
d. Shock within 24 hours of procedure or hospital discharge.

2. Hospitals participating in the "Special Project: Primary Angioplasty" must report in writing within 7 days any of the following events:
    a. Cerebrovascular accident. This is defined as acute neurological deficits recorded by clinical staff that persisted >24 hours. Report if these events occurred within 30 days after the catheterization but not clearly related to procedure.
    b. Any intracranial bleed within 30 days of the cardiac catheterization procedure.
    c. Recurrent Q wave or Non-Q wave MI during the index hospitalization.
    d. Vascular complications which occur within 24 hours of the cardiac catheterization procedure or hospital discharge. These are defined as:
        1. Hematoma > 4 cm
        2. Retroperitoneal bleed
        3. False aneurysm
        4. AV fistula
        5. Peripheral ischemic /nerve injury
        6. Hemolysis and hemolytic anemia.

See Attachment E for additional reporting information.

F. Data Collection
    1. Hospitals that participated in the C-PORT study shall:
        a. Continue to collect ***all*** the required data and patient follow-up for all patients that have been enrolled.
        b. Fully cooperate with the C-PORT Data Coordinating Center (MMRI) in the timely collection and submission of this data.
        c. Adhere to the C-PORT Manual of Operations with respect to patient follow-up, the handling and publication of data, and contact with the media.
    2. All hospitals participating in the Special Project (Phase I and II) will:
        a. maintain a log of all patients that present with a diagnosis of AMI or R/O AMI to the Emergency Department of the hospital and the treatment administered (Attachment G).
        b. collect and archive all pertinent data on site in an easily retrievable manner. The CDAC "Case Report Forms" (See Attachment F) can be utilized as a checklist for the care of patients having a primary

angioplasty procedure performed. These forms will not be collected by the Department.

c. follow-up on all patients entered into the Special Project at 1 month, 6 months and one year after the index hospitalization (Attachment F).

d. fax monthly report form (See Attachment H) to the Department.

G. Quality Assurance (QA)

1. Each hospital participating in the Special Project shall:

a. Establish a Joint Quality Assurance Committee (Joint QA Committee) with its collaborating tertiary hospital. The membership of the Joint QA Committee shall, at a minimum, include ***each*** of the following disciplines: physicians, nurses and administrators from ***both*** the Special Project hospital and the collaborating tertiary hospital.

b. Convene the Joint QA Committee at least twice a year to review the care provided to patients under the Special Project. This review process shall focus on patient outcomes and at a minimum include an assessment of the appropriateness of the selection of each patient entered into the Special Project; all complications; any adverse outcomes; number of patients requiring and reason for transfer to a tertiary facility; the technical quality of the catheterization and angioplasty procedures performed; and the "door to cath lab time" and "door to treatment time".

c. Develop and implement a plan of correction for any problems identified.

d. Develop a process for including the findings of the Joint QA Committee's review in the Special Project hospital's Quality Assurance Program.

e. Prepare a report of each meeting of the Joint QA Committee to be submitted to the Department within two weeks of each meeting of the Joint QA Committee.

2. All Staff (including, at a minimum, all interventional cardiologists, nurses and technicians) as well as representatives of the ED and CCU staffs shall participate in the Special Project QA process, attending a minimum of 1 meeting of the Joint QA Committee/year.

H. Clinical Research

Any hospital participating in the Special Project and wishing to participate in any clinical research relative to angioplasty shall consult with the Department prior to the initiation of the research study. After consultation with the Principle Investigator and other appropriate parties, the Department will determine and notify the Special Project hospital if the objectives of the research study and of the Special Project are consistent.

VIII. Operational Phases of the Special Project

A. Phase I:

1. Upon receipt of a letter of approval to participate, hospitals enter Phase I of the Special Project.

2. Hospitals that participated in the C-PORT study shall continue to meet the requirements relative to C-PORT (See VII, F, 1).

3. Data collection, required by the Department, will be complete and archived at the Special Project hospital. The data will be maintained in an easily retrievable manner to be retrieved when requested by the Department or any designated agent of the Department.

4. A peer review process will be conducted as each group of 25 patients, entered into the Special Project, is accrued at each participating hospital. Physicians designated by the Department will conduct the reviews. The fees for the services of these physicians will be paid to them by the relevant hospital. A written report of each of these peer reviews will be submitted to the Department and will include recommendations regarding the continuation of the Special Project relative to that specific site.
5. The Department, with the assistance of the ICSAC, will review the peer review group's report and recommendations and determine if the relevant hospital will be permitted to continue to participate in the Special Project.

B. Phase II:
   1. When each hospital participating in Phase I of the Special Project has performed 150 primary angioplasty procedures the Department, with the assistance of the ICSAC, will review the experience of that specific hospital and will determine *if* the hospital moves into Phase II of the Special Project.
   2. Upon receipt of a letter of approval from the Department, the participating hospital may enter Phase II of the Special Project.
   3. Hospitals that participated in the C-PORT study shall continue to meet the requirements relative to C-PORT (See VII, F 1).
   4. Each Special Project hospital will maintain a collaborative association with a tertiary hospital and a current, valid "Collaboration Agreement" with that same tertiary hospital. Each hospital participating in the Special Project will be required to continue to meet all of the requirements of the collaborative association as stipulated in VI.
   5. The Department may, from time to time, require review of a sample of patients cared for under the provisions of the Special Project.
   6. Hospitals must continue to meet *all* the requirements contained in VII *and* IX.

IX. Requirements for ongoing participation in the Special Project (Phase I and II) include:

A. ***All hospitals*** participating in the Special Project must:
   1. continue to perform a ***minimum*** of 300 diagnostic cardiac catheterizations/year.
   2. continue to operate the cardiac catheterization service at a ***minimum*** of 5 days/week and 8 hours/day.
   3. develop policies and procedures that will assure that all interventional cardiologists performing primary angioplasty procedures at the Special Project hospital will maintain an appropriate level of proficiency as a member of the team performing primary angioplasty at the Special Project hospital. These policies and procedures will detail the process the Physician Director will utilize to assure the establishment, maintenance and monitoring of the proficiency of each interventional cardiologist.
   4. maintain a collaborative association and a current, valid Collaboration Agreement with tertiary hospital including Joint Q A and staff education programs.
   5. perform a ***minimum*** of **36** primary angioplasty procedures/year. At least 30 of these angioplasty procedures must be *primary* angioplasty procedures (excluding patients that have "rescue angioplasty" procedures performed).

a. For hospitals participating in the Special Project on November 23, 1999:
    1. For the purpose of counting procedures, the "clock starts" on February 29, 2000. Within the 6 months following that date (by August 31st) each hospital would have to have performed 18 primary angioplasty procedures or will receive a warning that approval to participate in the Special Project may be withdrawn.
    2. Within the following 6 month period (by February 28, 2001), each site would have to have performed at least another 18 procedures or the program will be discontinued at that site.
    3. Each site must continue to perform 18 primary angioplasty procedures/6 months and a total of 36 primary angioplasty procedures/year or the program will be discontinued at that site.

b. For hospitals approved to participate in the Special Project after November 23, 1999:
    1. For the purpose of counting procedures, the "clock starts" 6 months after the date of the Department's notification of approval to the applicant hospital allowing them to participate in the Special Project. Twelve (12) months, from the date of the letter, the hospital will have to have performed 18 primary angioplasty procedures or will receive a warning that approval to participate in the Special Project may be withdrawn.
    2. Within the following 6 months (a total of 18 months from the date of the Department's letter of approval) the hospital would have to have performed at least another 18 procedures, a total of 36 primary angioplasty procedures or the program will be discontinued at that site.
    3. Each site must continue to perform 18 primary angioplasty procedures/6 months and a total of 36 primary angioplasty procedures/year or the program will be discontinued at that site.

B. **All physicians** performing primary angioplasty at a Special Project hospital must:
    1. continue to perform no fewer than 100 cardiac catheterization procedures/year (total diagnostic and therapeutic) of which at least 75 are angioplasty procedures.
    2. maintain credentials at a hospital at which that operator performs elective angioplasty procedures.

C. Inservice education
    1. All staff (including, at a minimum, all interventional cardiologists, nurses and technicians) must participate in the "C-PORT" training program.
    2. All staff (including, at a minimum, all interventional cardiologists, nurses and technicians) that are hired *after* the completion of the "C-PORT" training at the Special Project hospital will complete a training program that mirrors the "C-PORT" training program. The relevant collaborating tertiary and Special Project hospitals will develop this training program. The proposed training program will be submitted to the Department for approval prior to the implementation of the training program.
    3. Training of all staff (including, at a minimum, all interventional cardiologists, nurses and technicians) shall be performed on the intra-aortic balloon pump monthly. Staff that participated in the utilization of

the intra-aortic pump in patient care (at the Special Project hospital) during the previous month are exempt from this requirement.

4. All staff, including the interventional cardiologists, nurses and technicians must have a current ACLS certification.
5. Inservice programs will, at a minimum, be based upon needs identified through staff evaluations and the quality assurance process.

X. General Provisions

A. All hospitals must fully comply with all of the above conditions for continued participation in the Special Project; failure to do so will result in the withdrawal of approval to perform primary angioplasty.
B. The Department will convene all hospitals participating in the Special Project on a regular basis for the purpose of discussing and assessing the status of the implementation of the Special Project.
C. The Invasive Cardiac Services Advisory Committee (ICSAC) will review the reports and data submitted and advise the Department in its ongoing review of current policies and regulations relative to the Special Project.

REFERENCES:

The Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Manual of Operations (Version 7, 9/1/98)

Agency for Health Care Policy Research (AHCPR); Clinical Practice Guideline Number 10; Unstable Angina: Diagnosis and Management

MA Department of Public Health, Division of Health Care Quality; **Hospital-Based Adult Cardiac Catheterization Services Licensure Regulations** (105 CMR 130.900 through 130.982)

RESOURCES:

Cardiovascular Data Analysis Center (CDAC); Director: Richard E. Kuntz, M.D., MSc

Members of the Invasive Cardiac Services Advisory Committee (ICSAC)

The Atlantic Cardiovascular Patient Outcomes Research Team (Atlantic C-PORT); Director: Thomas Aversano, M.D.; Nurse Co-ordinator: Lynnet Tirabassi Aversano, RN, BSN